REMARKS/ARGUMENTS

No claims are amended by the instant response. Therefore, claims 1-26 remain pending.

Embodiments in accordance with the present invention relate generally to methods and systems for constructing models of the behavior of pharmacological entities. In particular, the pending claims relate to construction of a pharmacological model comprising pharmacokinetic/pharmacodynamic (PK/PD) elements:

> pharmacokinetics, which is the study of the processes by which a drug is absorbed, distributed, metabolized and eliminated by the body, and pharmacodynamics, which is the study of the action or effects of drugs on living organisms. (Emphasis added; page 1, lines 12-15)

An excerpt from Gabrielson and Weiner, "Pharmacokinetic and Pharmacodynamic Data Analysis" 3rd Ed., Apotekarsocieteten (2000), providing definitions of PK/PD principles, is being submitted herewith in a supplemental information disclosure statement.

As described extensively in the instant specification, models in accordance with embodiments of the present invention include PK/PD elements relating behavior of a drug or compound. For example, a "formulation" block represents the intention to administer a particular drug (i.e. a path of drug administration). (See ¶(39)) An "emax" block represents the most common model of how concentration causes an effect, wherein the effect of a drug approaches an asymptotic limit (Emax), as the drug concentration next to the receptor sites increases. (See ¶(63)).

Pending independent claim 1 accordingly recites:

> 1. A method for pharmacological computational model construction, comprising:
> (a) presenting a graphical user interface having a plurality of objects, each object representing one or both of a pharmacokinetic element and a pharmacodynamic element;
> (b) receiving instructions via the graphical user interface for connection of at least two of the objects;
> (c) displaying the at least two objects connected in accordance with the received instructions;
> (d) converting the at least two connected objects into equations corresponding to the pharmacokinetic and pharmacodynamic elements represented by the at least two connected objects, wherein the converting step (d) occurs substantially coincident with the object displaying step (c); and

(e) displaying the equations on the graphical user interface substantially coincident with the object displaying step (c).

The Examiner has rejected claims 1-4 and 14-15 as anticipated under 35 U.S.C. 102 by U.S. patent no. 6,381,562 to Keane ("the Keane patent"). These claim rejections are overcome as follows.

As an initial matter, the Examiner is reminded that claim 1 stands rejected as anticipated, and not merely obvious, in light of the Keane patent:

> [t]he distinction between rejections based on 35 U.S.C. 102 and those based on 35 U.S.C. 103 should be kept in mind. Under the former, the claim is anticipated by the reference. No question of obviousness is present. In other words, for anticipation under 35 U.S.C. 102, the reference must teach every aspect of the claimed invention either explicitly or impliedly. Any feature not directly taught must be inherently present. (Emphasis added; MPEP 706.02)

Here, the Keane patent fails to teach objects representing one or both of a pharmacokinetic element and a pharmacodynamic element.

The Keane patent relates to simulation of the bio-transport system of an organism. The modeling described by the Keane patent is based upon conventional physical principles governing the flow of fluids:

> Most bio-transport dynamics are governed by established first principles and physical relationships, for example, conservation of mass, conservation of momentum, conservation of energy, constitutive equations and other empirical relationships. The simulation model uses these relationships along with the user-specified characteristics to calculate bio-transport dynamics aspects such as flow rates, concentrations and pressures at different points in the configured simulation model at different points in time. (Emphasis added; col. 5, lines 29-38)

The Keane patent model thus considers basic physical properties of the fluid and the flow elements:

> Generally, an element is characterized in terms of its geometry and physical characteristics which may include, for example, shape, dimensions, orientation, elasticity, permeability and resistance to flow, just to name a few. The fluid associated with the element is characterized generally in terms of physical properties such as, for example, viscosity, heat capacity and density, just to name a few. (Emphasis added; col. 4, lines 45-51)

Thus at most, the Keane patent allows simplified modeling of the physical transport of a drug that has been introduced into an organism. However, the Keane patent says nothing regarding the absorption, elimination, or metabolization (i.e. pharmacokinetics) of such a transported drug, nor the action or effects of such a transported drug upon the organism (i.e. pharmacodynamics).

The lack of any teaching or suggestion in the Keane patent regarding modeling based upon pharmacokinetic or pharmacodynamic properties, is underscored by the very passages relied upon by the Examiner in rejecting the claims. For example, at col. 13, lines 40-45, the Keane patent merely describes including inputs and outputs to a modeled circulatory fluid flow system. At col. 16, lines 14-25, the Keane patent simply mentions some conditions (initial, boundary) and characteristics (fluid, material, element) of the "Fluid Flow Model". There is no teaching or suggestion here for the model of the Keane patent to consider the PK/PD principles recited in the pending claims.

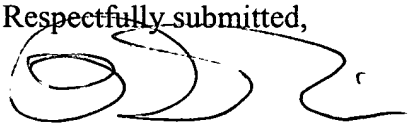
Based upon the failure of the Keane patent to teach every aspect of claims 1-4 and 14-15, it is respectfully asserted that these claims cannot be considered anticipated by the Keane patent. The anticipation rejections are improper and should be withdrawn.

Finally, the Examiner has relied upon the Keane patent in combination with U.S. patent application publication no. 2003/0156143 to Westenkow et al. ("the Westenkow application"), to reject the remaining claims as obvious. Specifically, the Examiner indicated the Keane patent "teaches plotting one or more selected variables upon a graph and updating the graph". (Office Action Mailed December 22, 2004, page 5, lines 3-4)

As a threshold matter, Applicant questions the availability of the Westenkow application as prior art to the instant case. Specifically, the effective date of the Westenkow application is August 21, 2003, its date of publication. This publication date is over two years after the March 30, 2001 filing date of the instant application. Before providing any comment on the relevance of the Westenkow application to patentability of the instant case, applicant respectfully requests that the Examiner indicate the specific section of 35 U.S.C. 102 under which the Westenkow' patent qualifies as prior art to the instant application.

In view of the foregoing, Applicant believes all claims now pending in this Application are in condition for allowance. The issuance of a formal Notice of Allowance at an early date is respectfully requested. If the Examiner believes a telephone conference would expedite prosecution of this application, please telephone the undersigned at 650-326-2400.

Respectfully submitted,



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